From: <u>Devlin, Robert</u>

To: Maryann Bassett; Montilla, Tracey; CN=Heidi Hiers/OU=RTP/O=USEPA/C=US@EPA; Ghio, Andrew; Martha

Carraway; Diaz-Sanchez, David

Subject: Warren Lux response to adverse event report **Date:** Monday, October 25, 2010 10:30:00 AM

---- Forwarded by Robert Devlin/RTP/USEPA/US on 10/25/2010 10:28 AM -----

From: Warren Lux/DC/USEPA/US

To: Robert Devlin/RTP/USEPA/US@EPA
Cc: Howard Kehrl/RTP/USEPA/US@EPA

Date: 10/21/2010 12:51 PM

Subject: Re: IRB response to adverse event report

Bob,

PS: With regard to resuming exposures in this study, you have IRB clearance to proceed, and I concur with the IRB's determination.

Warren

Warren Lux, M.D.

Human Subjects Research Review Official and Director, Program in Human Research Ethics U.S. Environmental Protection Agency Ronald Reagan Building - Room 41248 202-564-2677 or 202-564-3746 (direct)

From:

Warren Lux/DC/USEPA/US

To:

Robert Devlin/RTP/USEPA/US@EPA

Cc:

Howard Kehrl/RTP/USEPA/US@EPA

Date: 10/21/2010 12:47 PM

Subject: Re: IRB response to adverse event report

Bob,



Warren

.....

Warren Lux, M.D.

Human Subjects Research Review Official and Director, Program in Human Research Ethics U.S. Environmental Protection Agency Ronald Reagan Building - Room 41248 202-564-2677 or 202-564-3746 (direct)

From: Robert Devlin/RTP/USEPA/US

To: Warren Lux/DC/USEPA/US@EPA

Cc: Howard Kehrl/RTP/USEPA/US@EPA

Date: 10/20/2010 03:27 PM

Subject: IRB response to adverse event report



---- Forwarded by Robert Devlin/RTP/USEPA/US on 10/20/2010 03:24 PM -----

From: IRB <irb_no_reply@mailserv.grad.unc.edu>

To: Robert Devlin/RTP/USEPA/US@EPA

Cc: Mike Schmitt/RTP/USEPA/US@EPA, Candice Bailey/RTP/USEPA/US@EPA, Robert

Truckner/RTP/USEPA/US@EPA, wsimmons+IRB@med.unc.edu

Date: 10/20/2010 02:44 PM Subject: IRB Notice

To: Robert Devlin

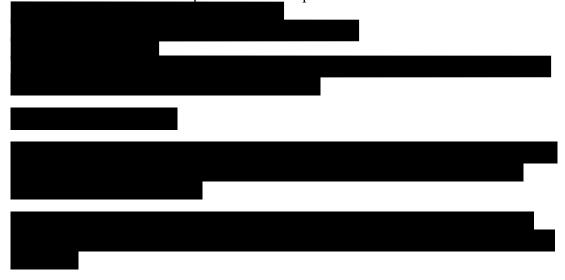
Pediatrics CB: 7315

From: Biomedical IRB

Authorized signature on behalf of IRB

Date: 10/20/2010

RE: IRB review of Unanticipated Problem report



CC:

Mike Schmitt, Environmentally Protection Agency Candice Bailey, Epa Robert Truckner, (EPA), Non-IRB Review Contact Wanda Simmons, (CTRC), Non-IRB Review Contact